**REMARKS**

In the Office Communication mailed February 13, 2007, the Examiner stated, "The reply filed on 14 December 2006 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant did not address the requirement for sequence identifiers in the Brief Description of Fig. 2-4 for each sequence in the figures and from the paragraphs starting on page 40, line 24, pg 108, line 4, and pg 11, line 17." Now the Applicants amend the Specification in the manner requested by the Examiner. For the Examiner's convenience, the Response submitted on December 14, 2006 is provided below.

Claims 23-30 are pending. In the Final Office Action mailed August 10, 2006, the Examiner rejected claims 23-30 as being nonenabled and as lacking an adequate written description and claim 29 as being indefinite. Each rejection is addressed below.

**I. Claim 29 is Definite**

Claim 29 has been rejected as indefinite. Claim 29 has been amended to specify that the plant seed is transgenic. It is believed that this amendment obviates the Examiner's rejection.

**II. The Claims are Enabled**

The Examiner argues that the claims, while being enabling for a nucleic acid encoding SEQ ID NO:2, does not provide enablement for a vector comprising any nucleic acid that is at least 90% homologous to SEQ ID NO:1 or 3. Office Action at p. 3. The Examiner goes on to argue that the specification "fails to teach how to make any nucleic acid that is at least 90% homologous to SEQ ID NO:1 or 3, wherein the nucleic acids encode AtFtn2 proteins." Office Action, p. 4.

The Examiner's attention is respectfully directed to the Federal Circuit's recent holding in Falkner v. Inglis, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). There, the Board of Appeals and Interferences (the Board) found, and the Federal Circuit agreed, that the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art. Id. at 1366. The parties in Falkner acknowledged that the person of skill in the art "as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the 'needed technical skill to practice the experimentation described in the scientific literature relating to recombinant virus, including poxvirus.'" Id. The Board agreed with the parties' stipulation as to level of skill. Id.

In the instant case, the Examiner has failed to define the level of skill in the art. In making a nonenablement rejection, the burden is on the Examiner to make a *prima facie* case of nonenablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Wright,* 27 USPQ2d at 1513).

The Examiner has not made properly reasoned and supported statements explaining Applicant's alleged failure to comply with 35 U.S.C. §112. Indeed, it is impossible to do so without establishing the level of skill in the art which the Examiner has failed to do in this case.

In the instant case, the level of skill in the art is certainly as high as that noted in Ealkner. The person of skill in the art would have 5-10 years experience creating recombinant genes for expression in transgenic plants, including Ftn2 genes, would be familiar with the literature on expression of genes in plants and the screening of Ftn2 genes for expression in plants, the use of vectors for the expression of heterologous genes in plants, and having the needed technical skill to practice the experimentation described in the scientific literature relating to expression of Ftn2 genes in plants. In short, the level of skill in the art is high. The Examiner has falied to take this into account in rejecting the pending claims.

The Examiner further argues that making conservative substitutions in a sequence does not produce predictable results. Office Action, p. 4. However, the state of the art at the time the application was filed was not concerned with making predictable changes. Indeed, the state of the art was to make changes, both conservative and nonconservative, and then to test the resulting sequence, for example, by expression in a transgenic plant. This type of experimentation was clearly within the skill in the art. In Falker, the Federal Circuit noted the following from the Board's decision:

> The Board observed that "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation."

Id. Likewise, in the instant application, great expenditures of time and effort would be ordinary in the field of screening genes and expressing them in transgenic plants. The Examiner argues that the present invention would require making and analyzing $19^{801}$ sequences. That what it would require to analyze **all possible** sequences. This argument has no merit. A person of skill in the art would recognize that many suitable sequences falling within the claimed range of 90% homology and that have the claimed function of encoding a product that functions in division of a photosynthetic prokaryote or a plastid can be identified by using experimental methods well within the skill of the art. Indeed, the Examiner has ignored the

functional limitation in the claims in making the rejection. The person of skill in the art would use known methods of modifying SEQ ID NO:1 and 3 and known methods for screening the resulting sequences for the desired activity. An extensive description of the state of the art in screening for desired sequences that are 90% homologous to SEQ ID NO.: 1 and 3 is provided at pages 55-60 of the specification. By using these methods, a person of skill in the art could identify many sequences having 90% homology to SEQ ID NO.: 1 and 3.

For the foregoing reasons, the Examiner has failed to establish a prima facie case of enablement and the enablement rejection should be withdrawn.

## III. The Claims are Supported by an Adequate Written Description

The Examiner has also rejected the claims because they allegedly lack an adequate written description. The Examiner asserts that "the essential feature of the claims is a nucleic acid that is at least 90% homologous to SEQ ID NO:1 or 3 and encodes a product that functions in division of a prokaryote or a plastid. As the protein and its activity are novel, there is no well developed field of prior art."

The Applicants respectfully disagree. As described above, a person of skill in the art would have extensive experience in modifying genes such as the Ftn2 gene and expressing the modified gene in a transgenic plant. The Examiner's attempt to narrow the experience of a person of skill in the art is misguided.

The Examiner then argues that "there is no description of the structure required for the recited function, and no description of the necessary and sufficient structural elements of a protein with Ftn2 function." Again, this argument has no basis. The claims specifically recite the DNA structures SEQ ID NO:1 and 3. That is all the structure that is required by the law.

The Examiner's attention is respectfully directed to the Federal Circuit's recent holding in Falkner v. Inglis, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). In that case, the Federal Circuit specifically held that "Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." Id. at 1367. The Federal Circuit went on to explain that:

> Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:
>
> The descriptive text needed to meet these requirements varies with the nature and

> scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science. Id. at 1357.

> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

Id. at 1367-68. The Federal Circuit then specifically held that "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." Id.

Falkner is instructive on two points. First, the reference to the **DNA structure** is what is required by the law if the DNA structure is not in the prior art. Here, Applicants have met that requirement by disclosing and claiming the **DNA structures** SEQ ID NO:1 and 3. Second, since the written description requirement "is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field." As described in detail above, making and identifying sequences with 90% homology to SEQ ID NO:1 and 3 is well within the skill in the art.

For the foregoing reasons, the applicants were in possession of the invention as claimed and the written description rejection should be withdrawn.

## IV. Conclusion

All grounds of rejection of the Office Communication of February 13, 2007 and the Office Action of August 10, 2006 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicant's new claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: March 13, 2007 By: _____

Robert A. Goetz
Registration No. 55,210

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
415.904.6500